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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,034	10/03/2006	Fraser W. Scott	034205.003 (08899427US1)	5076

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
03/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/597,034	SCOTT ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009 and 04 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *6-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence Notice to Comply*.

DETAILED ACTION

1. Applicant's election without traverse of Group I filed 5/22/09 is acknowledged.

2. Claims 6-35 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b), as being drawn to a non-elected species and inventions.

Claims 1-5 are under examination.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132. As set forth previously, the Sequence Listing and Computer eadable Format must list the Inventors at line <110>.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the

invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of the "diabetogenic epitope" of Claim 1.

The specification at page 10 defines said epitope as:

> "By the term "diabetogenic epitope" it is meant a sequence of amino acids which is capable of being bound by an antibody produced by a subject, for example, but not limited to a human subject, the antibody involved in an immune reaction associated with diabetes or diabetes pathogenesis. The epitope may comprise a linear sequence of amino acids which is recognized by the antibody, or the epitope may adopt a higher ordered structure, for example, a three dimensional structure as is known in the art, and the antibody may bind to the three dimensional structure of the epitope."

One of skill in the art would realize that this definition encompasses *all* possible epitopes given that there is no limitation to epitopes involved with diabetes. Further, essentially all proteins are capable of being bound by an antibody in some context. Accordingly, this "definition" provides no limitations at all. Clearly there is no common structure and, as any protein or peptide can be bound by an antibody, neither is there a meaningful common function. Turning to the disclosure for representative species of the claimed epitopes, it is unclear that *any* (related to diabetes) are disclosed. The specification discloses "*Identification of epitopes*" at page 41, but curiously, no actual epitopes are disclosed. Presumably the peptide of SEQ ID NO:1 is intended as one of the claimed epitopes but it is unclear how it was derived and whether or not it is actually related to diabetes. Also note that the definition of the claimed epitopes set forth above specifically includes three dimensional, non-linear, epitopes that could not be obtained through the disclosed method of peptide epitope mapping. Clearly then, neither specific structure and function, nor an adequate number of representative species of the claimed "diabetogenic epitopes" are disclosed in the instant specification. One of skill in the art would therefore conclude that the specification fails to adequately describe, and Applicant was not in possession of, said epitopes. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by MacFarlane et al. (2003, IDS).

MacFarlane et al. teaches a Glb1 isoform, the protein expressed from clone WP5212, comprising the EEQLRELRRQ amino acid sequence of SEQ ID NO:1 (see particularly, EXPERIMENTAL PROCEDURES, page 55, wherein the protein is expressed). The reference further teaches the protein attached to a support (see particularly *One and Two-Dimensional Western Blotting*, page 57, wherein the peptide is attached to nitrocellulose).

The reference clearly anticipates the claimed invention.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over MacFarlane et al. (2003, IDS) in view of U.S. Patent No. 6,803,221.

MacFarlane et al. has been discussed above.

The reference teaching differs from the claimed invention in that it does not teach the diabetogenic epitope of Glb1 further comprising a protein or peptide that does not occur in nature.

The ‘221 patent teaches that proteins or peptides of interest are routinely attached to other proteins or peptides for numerous reasons (see the entire document). Specifically, proteins or peptides are routinely attached to histidine hexamers (which would not be considered to be naturally

occurring) to facilitate the purification of the protein or peptide (see particularly, column 14, lines 50-61).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to fuse the histidine hexamer of the '221 patent to the Glb1 protein of MacFarlane et al. to facilitate the purification of the recombinant protein such that it might be used in the autoantibody assays of MacFarlane et al..

10. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacFarlane et al. (2003, IDS) in view of U.S. Patent No. 6,927,041.

MacFarlane et al. has been discussed above.

The reference teaching differs from the claimed invention in that it does not teach the diabetogenic epitope of Glb1 attached to a support such as a bead, a plate, or a slide.

The '041 patent teaches that proteins or peptides of interest are routinely attached to a bead, a plate, or a slide to facilitate separation and to accommodate assays (see particularly column 22, line 60 – column 23, line 15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to attach the Glb1 protein of MacFarlane et al. to the bead, plate, or slide of the '221 patent to the Glb1 protein of MacFarlane et al. to facilitate separation and to accommodate assays.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0841.

13. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

/G.R. Ewoldt/
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